



Fast Track Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-191
Regulation title	State Plan for the Children with Special Health Care Needs Program
Action title	Amend regulation as a result of periodic review
Date this document prepared	September 6, 2011

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.

Periodic review for 12VAC5-191 was conducted pursuant to Executive Order 14 (2010). The periodic review began on April 6, 2011. Nine public comments were received. Four of the comments were general support for the regulation. Four of the comments were specific to the Child Development Services Network requesting that these services needed to be increased. One comment was specific text recommendations. It was determined that this regulation needed several amendments to update references to other regulations and laws and modify references where organizational structures, names, or functions have changed since the regulation was promulgated in 2007.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

The State Health Commissioner approved the proposed regulatory changes to 12VAC5-191, State Plan for the Children with Special Health Care Needs Program, on August 12, 2011 on behalf of the State Board of Health.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.

Section 32.1-12 of the Code of Virginia authorizes the Board of Health to make, adopt, promulgate and enforce regulations.

Section 32.1-77 authorizes the Board of Health to prepare, amend, and submit state plans for maternal and child health services and children's specialty services pursuant to Title V of the United States Social Security Act to the U.S. Secretary of Health and Human Services. Section 32.1-77 authorizes the State Health Commissioner to administer the plan and to receive and expend federal funds for the administration of the plan in accordance with applicable federal and state laws and regulations.

Section 32.1-64.1 of the Code of Virginia mandates the Commissioner of Health to "establish and maintain the Virginia Hearing Impairment Identification and Monitoring System...for the purpose of identifying and monitoring infants with hearing impairment to ensure that such infants receive appropriate early intervention through treatment, therapy, and education." Subsection D mandates the Board to establish regulations for the screening. Subsection F authorizes the Board of Health to promulgate "rules and regulations as may be necessary to implement this identification and monitoring system".

Section 32.1-65 of the Code of Virginia mandates certain newborn screening testing of all infants, except for those exempted from testing by law, for specified disorders.

Section 32.1-66 of the Code of Virginia mandates the Commissioner of Health to "notify forthwith the attending physician of any newborn screening test results that indicate a suspicion of a disorder and to perform or provide for any additional testing required to confirm or disprove the diagnosis" of the specified disorders.

Section 32.1-67 of the Code of Virginia mandates the Board of Health to recommend procedures for the treatment of disorders identified by a newborn screening test.

Section 32.1-68 of the Code of Virginia mandates the Commissioner, in cooperation with local health directors, to "establish a voluntary program for the screening of individuals for the disease of sickle cell anemia or the sickle cell trait and for such other genetically related diseases and genetic traits and inborn errors of metabolism as the Board may deem necessary. The Board shall review the program from time to time to determine the appropriate age and the method of screening for such conditions or traits in the light of technological changes. The screening program shall include provisions for education concerning the nature and treatment of sickle cell anemia, other genetically related diseases and inborn errors of metabolism and a post-screening counseling program for the treatment of any person determined to have such a condition. The program may include the provision of laboratory testing."

Section 32.1-69.1 of the Code of Virginia mandates the Commissioner to "establish and maintain a Virginia Congenital Anomalies Reporting and Education System using data from birth certificates filed with the State Registrar of Vital Records and data obtained from hospital medical records. The chief administrative officer of every hospital, as defined in §32.1-123, shall make or cause to be made a report

to the Commissioner of any person under two years of age diagnosed as having a congenital anomaly.” Subsection B mandates the Board to promulgate regulations “as may be necessary to implement this reporting and education system”. These regulations may include “scope of information to be collected” and “relationships between the reporting and education system and other agencies”.

Section 32.1-89 of the Code of Virginia mandates the Board of Health to establish “a program for the care and treatment of persons suffering from hemophilia and other related bleeding diseases” who cannot pay for the entire cost of their needed medical care. Subsection B authorizes the Board of Health to provide services “through cooperative agreements with medical facilities or other appropriate means.” This subsection also states that charges for persons receiving care shall be determined by the Board of Health.

All of these authorized and mandated programs serve children with special health care needs. Separate regulations 12VAC5-71 “Regulations Governing Virginia Newborn Screening Services” and 12VAC5-80 “Regulations for Administration of the Virginia Hearing Impairment Identification and Monitoring System” exist for these programs. Relationships among the programs are addressed in 12VAC5-191.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

A periodic review of 12VAC5-191 was conducted starting on April 6, 2011. The public comment period ended on May 30, 2011. An ad-hoc regulatory workgroup met on June 2, 2011 to review the regulation and public comments.

The workgroup recommended to amend the regulation through the fast-track process to correct references to other regulations, laws, and organizational entities which have changed since the regulation went into effect in 2007.

This regulation is essential to outline program services for children with special health care needs that are made available to eligible residents within available appropriations and to help qualify for federal Title V and other available funds for plan administration. Although the program is neither an entitlement nor a federal, state, or local public benefit, the program does offer certain services and assistance, contingent upon adequate funding, which may affect the rights of individuals.

Other state-mandated initiatives, such as the Virginia Newborn Screening System, Virginia Congenital Anomalies Reporting and Education System, Virginia Sickle Cell Awareness Program, and Pediatric Comprehensive Sickle Cell Clinic Network also identify and serve children with special health care needs. These programs, several of which have separate regulations, are now referenced in this regulation as well.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

Please note: If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall (i)

file notice of the objections with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Executive Order 14 allows state agencies to use a fast-track rule making process to expedite regulatory changes that are expected to be non-controversial. The amendments to 12VAC5-191-10, 40, 80, and 210 are not substantive changes. These amendments will update certain terms and references to other regulations, laws, and organizational entities which have changed since 2007. The amendments to 12VAC 5-191-90 and 250 are substantive but are not expected to be controversial.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the “Detail of changes” section.)

The amendments to 12VAC5-191-90 remove multiple specific citations to privacy and confidentiality laws and substitute the term “all applicable federal and state laws and regulations”. The amendments to 12VAC5-191-250 reflect changes in organizational structure and functions due to changes in grant funding and activities.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

If there are no disadvantages to the public or the Commonwealth, please indicate.

The primary advantage of amending this regulation is to keep references within the regulation current and up to date. There are no primary disadvantages.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

The proposed changes do not contain any requirements that are more restrictive than federal requirements contained in the regulation.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

No locality is particularly affected by the proposed changes.

Regulatory flexibility analysis

Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The alternative regulatory methods are not applicable.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	No costs will be incurred due to the proposed amendments.
Projected cost of the <i>new regulations or changes to existing regulations</i> on localities.	No costs will be incurred by localities due to the proposed amendments.
Description of the individuals, businesses or other entities likely to be affected by the <i>new regulations or changes to existing regulations</i>.	No individuals, businesses, or other entities will be affected due to the proposed amendments.
Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	None
All projected costs of the <i>new regulations or</i>	None

<p>changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	
<p>Beneficial impact the regulation is designed to produce.</p>	<p>Regulation citations and terms will be up to date.</p>

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

This regulation is essential to outline program services for children with special health care needs that are made available to eligible residents within available appropriations and to help qualify for federal Title V and other available funds for plan administration. Although the program is neither an entitlement nor a federal, state, or local public benefit, the program does offer certain services and assistance, contingent upon adequate funding, which may affect the rights of individuals.

Other state-mandated initiatives, such as the Virginia Newborn Screening System, Virginia Congenital Anomalies Reporting and Education System, Virginia Sickle Cell Awareness Program, and Pediatric Comprehensive Sickle Cell Clinic Network also identify and serve children with special health care needs. All of these authorized and mandated programs serve children with special health care needs. Separate regulations 12VAC5-71 “Regulations Governing Virginia Newborn Screening Services” and 12VAC5-80 “Regulations for Administration of the Virginia Hearing Impairment Identification and Monitoring System” exist for these programs. Relationships among these programs are addressed in 12VAC5-191.

The Office of the Attorney General deemed that regulations were necessary to govern this program in February 2004. The Virginia Department of Health had explored use of guidance documents, applicable federal directives, the annual plan submitted for receipt of federal Title V funds, and program policy and procedure guides as alternatives to the promulgation of regulations. This regulation was promulgated in 2007. A periodic review was conducted in 2011 with the recommendation to amend the current regulation.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed changes will not have any impact on the institution of the family and family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact in each section. Please describe the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all provisions of the new regulation or changes to existing regulations between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
10		"Division" means the Division of Child and Adolescent Health	"Division" means the Division of Child and Family Health due to internal reorganization
40		Listing of "Pediatric Screening and Genetics Services" under list of networks and services	Change to "Genetics and Newborn Screening Services" to reflect name change in organizational structure. Reformatting of subsections to make new subsection "C" entitled "Networks and Services". Subsequent subsections re-lettered.
80		"The director shall consider all written information and may confer, as deemed necessary, with the department's adjudication officer in the Office of Family Health Services or other relevant experts."	Removal of "in the Office of Family Health Services" to reflect organizational change and placement of adjudication officer.
90		Privacy of personal health information and confidentiality of medical records shall done in accordance with "§§ 2.2-3700 through 2.2-3705.1, 2.2-3705.5, 2.2-3800 through 2.2-3809, 32.1-40, 32.1-41, 32.1-64.2, 32.1-67.1, 32.1-69, 32.1-69.2, 32.1-127.1:03, and 32.1-127.1:04 of the Code of Virginia; the federal Health Insurance Portability and Accountability Act of 1996 (42 USC §§ 1320 d et seq. and 45 CFR Part 164); and Title V of the	Removal of specific citations and substitution of "all applicable federal and state laws and regulations" as laws and regulations regarding privacy and confidentiality of personal health information may change more frequently with the implementation of electronic medical records and health care reform.

		Social Security Act (42 USC §§ 701-710, Subchapter V, Chapter 7 and 42 CFR 51a.6)."	
210		Section title currently reads: "Score and content of the Child Development Services Program"	Correction of error from "Score" to "Scope"
250		Section title currently reads: "Pediatric Screening and Genetic Services"	Change section title to " Genetics and Newborn Screening Services" to reflect name change in organizational structure
250		Section currently reads: "The Pediatric Screening and Genetics Services unit works to improve the health of children and families by preventing birth defects and developmental disabilities, promoting optimal child development, and promoting health and wellness among children and adolescents living with disabilities. Pediatric Screening and Genetics Services include several programs, services, and projects, two of which are the Virginia Newborn Screening System and the Virginia Congenital Anomalies Reporting and Education System.	Removal of "Pediatric Screening and Genetics Services" and substitution of "Genetics and Newborn Screening Services" to reflect name change in organizational structure. Removal of phrases: " preventing birth defects and developmental disabilities,"; "and promoting health"; "living with disabilities"; and "include several programs, services, and projects, two of which are" to accurately reflect current program activities due to changes in grant funding.

For new chapters, use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements

The following public comments were received during the periodic review public comment period from May 9, 2011 through May 30, 2011.

Commenter	Comment	Agency response
Dr. William E Lynch, PsyD, Child and Adolescent Psychological Services	Expresses support for Child Development Services Program and concern for delays in evaluations and services provided. Requests that if any amendment is made that these services be increased not decreased.	The regulation does describe services provided under the Child Development Services Program. The regulation does not, however, address specific numbers of clinics or numbers of clients served. The regulation does not address which services will be decreased or increased. The regulation states that services will be provided within available funding. The Children with Special Health Care Needs Program has not received funding increases.
Tonya Boozer,	Expresses support for Child	Same response as above.

Chaplin Youth Center	Development Services Program. States that other Medicaid providers have at least a six month wait and do not offer the level of services provided by the Child Development Clinic. Requests that services not be reduced and to consider expansion of services.	
Susan Groom, Winchester Public Schools	Expresses support for Child Development Clinics and states that more clinics are needed across the state to meet needs.	Same response as above.
Clermont Ferrand	Expresses support for Child Development Clinics and states that more clinics are needed across the state to meet needs.	Same response as above.
Chad Peterson, Prosperity Health	General support for periodic review process and health care initiatives.	Acknowledgement of support.
Ketakiseo	General support for regulation.	Acknowledgement of support.
Uma	Support for regulation passing to help children.	Acknowledgement of support.
Angina Pectoris	General support for information.	Acknowledgement of support.
Sheila K.W. Elliott, Pharm. D., President AFGE Local 2328	Specific suggestions to regulatory text including adding examples of enabling services in definition; listing programs requiring financial eligibility; requiring appellant to speak to final decision maker; placing timelines on notification of closure or transfer; and general edits. Questions if physical basis requirement means that the program (Care Connection for Children) is for those with physical disabilities versus mental illness.	Comments considered during periodic review. Several comments already incorporated into current text. Enabling services and financial eligibility requirements listed under each program. Appellants may speak to final decision maker although this is not required. Timelines for closure or transfer will not be placed in regulation consistent with 12VAC5-200 which governs general health department services. Physical disability is required for eligibility for Care Connection for Children.